

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

ALLELE BIOTECHNOLOGY AND  
PHARMACEUTICALS, INC.,

Plaintiff,

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

**STIPULATED  
CONFIDENTIALITY  
AGREEMENT AND  
PROTECTIVE ORDER**

Case No. 7:20-cv-08255 (PMH) (AEK)

PHILIP M. HALPERN, United States District Judge:

WHEREAS, all the parties to this action (collectively the “Parties” and individually a “Party”) request that this Court issue a protective order pursuant to Federal Rule of Civil Procedure 26(c) to protect the confidentiality of nonpublic and competitively sensitive information that they may need to disclose in connection with discovery in the above captioned action;

WHEREAS, the Parties, through counsel, agree to the following terms; and

WHEREAS, this Court finds good cause exists for issuance of an appropriately tailored confidentiality order governing the pretrial phase of this action,

IT IS HEREBY ORDERED that any person subject to this Order<sup>+</sup> – including without limitation the Parties to this action (including their respective corporate parents, successors, and assigns), their representatives, agents, experts and consultants, all third parties

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<sup>1</sup> A redline showing the differences between this Order and the Court’s Model Protective Order (available at [https://www.nysd.uscourts.gov/sites/default/files/practice\\_documents/PMH%20Halpern%20-%20ModelProtectiveOrder.pdf](https://www.nysd.uscourts.gov/sites/default/files/practice_documents/PMH%20Halpern%20-%20ModelProtectiveOrder.pdf)) is attached as Exhibit C.

providing discovery in this action, and all other interested persons with actual or constructive notice of this Order — will adhere to the following terms, upon pain of contempt:

1. With respect to “Discovery Material” (i.e., information of any kind produced or disclosed in the course of discovery in this action) that a person has designated pursuant to this Order, no person subject to this Order may disclose such designated Discovery Material to anyone else except as this Order expressly permits:

2. The Party or person producing or disclosing Discovery Material (“Producing Party”) may designate as “Confidential” only the portion of such material, unless the entire document contains Confidential Discovery Material, that it reasonably and in good faith believes consists of:

- (a) previously non-disclosed financial information (including without limitation profitability reports or estimates, percentage fees, design fees, royalty rates, minimum guarantee payments, sales reports, and sale margins);
- (b) previously non-disclosed material relating to ownership or control of any non-public company;
- (c) previously non-disclosed business plans, product-development information, or marketing plans;
- (d) any information of a personal or intimate nature regarding any individual;  
or
- (e) any other category of information this Court subsequently affords confidential status.

3. The Producing Party may designate as “Highly Confidential” only the portion of such material, unless the entire document contains Highly Confidential Discovery Material, that it reasonably and in good faith believes consists of:

- (a) information considered to be most sensitive by the party, including but not limited to trade secret or other confidential research, development, financial, or other commercial information; or
- (b) current or ongoing trade secrets and other commercially sensitive research and development or technical data or information, including for past, present, and future products and projects.

4. With respect to the designated portion of any Discovery Material other than deposition transcripts and exhibits, the Producing Party or its counsel may designate such portion by: (a) stamping or otherwise clearly marking as “Confidential” or “Highly Confidential” the protected portion in a manner that will not interfere with legibility or audibility; and (b) producing for future public use another copy of said Discovery Material with the confidential information redacted. When a document is Confidential or Highly Confidential in its entirety, such document should be marked “Confidential” or “Highly Confidential” on the bottom of each page.

5. A Producing Party or its counsel may designate deposition exhibits or portions of deposition transcripts under this Order either by: (a) indicating on the record during the deposition that a question calls for Confidential or Highly Confidential information, in which case the reporter will bind the transcript of the designated testimony in a separate volume and mark it as “[Highly] Confidential Information Governed by Protective Order”; or (b) notifying the reporter and all counsel of record, in writing, within 30 days after a deposition has concluded,

of the specific pages and lines of the transcript that are to be designated “Confidential” or “Highly Confidential,” in which case all counsel receiving the transcript will be responsible for marking the copies of the designated transcript in their possession or under their control as directed by the Producing Party or that person’s counsel. During the 30-day period following a deposition, all Parties will treat the entire deposition transcript as if it had been designated as “Highly Confidential” under this Order.

6. If at any time before the trial of this action a Producing Party realizes that it should have designated under this Order some portion(s) of Discovery Material that it previously produced without limitation, the Producing Party may so designate such material by so apprising all prior recipients in writing. Thereafter, this Court and all persons subject to this Order will treat such designated portion(s) of the Discovery Material in accordance with said designation.

7. Nothing contained in this Order will be construed as: (a) a waiver by a Party or person of its right to object to any discovery request; (b) a waiver of any privilege or protection; or (c) a ruling regarding the admissibility at trial of any document, testimony, or other evidence.

8. Where a Producing Party has designated Discovery Material as Confidential, other persons subject to this Order may disclose such information only to the following persons:

- (a) outside counsel retained specifically for this action, including any paralegal, clerical, or other assistant that such outside counsel employs and assigns to this matter;

(b) two total designated Party Representatives (inclusive of those designated under Section 9(b)), who, because of their duties and responsibilities, require access to Confidential Discovery Material. Designated Party Representatives are to be designated according to the following procedure: During the pendency of this action, a Party that seeks to designate a Party Representative or designate a replacement Party Representative with a new designee, must first make a written request by execution of the declaration in the form annexed as Exhibit B hereto to the other Party. A Party that makes a request to designate or replace a designated Party Representative and provides an executed and completed Exhibit B to the other Party's outside counsel may disclose Confidential Discovery Material to the newly designated Party Representative after ten (10) days of delivering the executed Exhibit B (as calculated by Fed. R. Civ. P. 6), unless within that ten (10) day period, the Party receives a written objection from the objecting Party. Any such objection must set forth in detail the grounds on which such objection is based and be made in good faith. A Party that receives a timely written objection must meet and confer with the objecting Party to attempt to resolve the matter. Following the meet and confer, the objecting Party may apply to the Court for a protective order or other appropriate relief no later than fifteen (15) days (as calculated by Fed. R. Civ. P. 6) after receipt of the executed declaration in the form annexed as Exhibit B hereto;

- (c) outside vendors or service providers (such as copy-service providers, jury consultants, and document-management consultants) that counsel hire and assign to this matter;
- (d) any mediator or arbitrator that the Parties engage in this matter or that this Court appoints, provided such person has first executed a Non-Disclosure Agreement in the form annexed as an Exhibit hereto;
- (e) as to any document, its author, its addressee, and any other person indicated on the face of the document as having received a copy;
- (f) any person a Party retains to serve as an expert witness or otherwise provide specialized advice to counsel in connection with this action, provided such person has first executed a Declaration to be Bound by Protective Order in the form annexed as Exhibit B hereto after ten (10) days of delivering the executed Exhibit B (as calculated by Fed. R. Civ. P. 6), unless within that ten (10) day period, the Party receives a written objection from the objecting Party. Any such objection must set forth in detail the grounds on which such objection is based and be made in good faith. A Party that receives a timely written objection must meet and confer with the objecting Party to attempt to resolve the matter. Following the meet and confer, the objecting Party may apply to the Court for a protective order or other appropriate relief no later than fifteen (15) days (as calculated by Fed. R. Civ. P. 6) after receipt of the executed declaration in the form annexed as Exhibit B hereto;

- (g) stenographers engaged to transcribe depositions the Parties conduct in this action; and
- (h) this Court, including any appellate court, its support personnel, and court reporters.

9. Where a Producing Party has designated Discovery Material as Highly Confidential, other persons subject to this Order may disclose such information only to the following persons:

- (a) outside counsel retained specifically for this action, including any paralegal, clerical, or other assistant that such outside counsel employs and assigns to this matter;
- (b) two total designated Party Representatives (inclusive of those designated under Section 8(b)), who, because of their duties and responsibilities, require access to Highly Confidential Discovery Material, provided that such designated Party Representative have no current involvement and will not have involvement for the duration of this action in competitive decision making or the prosecution of any patent or patent application concerning (i) mNeonGreen or any fluorescent agent or (ii) anti-SARS-CoV-2 antibodies. This prosecution bar shall begin when access to Highly Confidential Discovery Material is first received by the affected individual and shall end one (1) year after final termination of this action.

Designated Party Representatives are to be designated according to the following procedure: During the pendency of this action, a Party that seeks to designate a Party Representative or designate a replacement Party

Representative with a new designee, must first make a written request by execution of the declaration in the form annexed as Exhibit B hereto to the other Party. A Party that makes a request to designate or replace a designated Party Representative and provides an executed and completed Exhibit B to the other Party's outside counsel may disclose Highly Confidential Discovery Material to the newly designated Party Representative after ten (10) days of delivering the executed Exhibit B (as calculated by Fed. R. Civ. P. 6), unless within that ten (10) day period, the Party receives a written objection from the objecting Party. Any such objection must set forth in detail the grounds on which such objection is based and be made in good faith. A Party that receives a timely written objection must meet and confer with the objecting Party to attempt to resolve the matter. Following the meet and confer, the objecting Party may apply to the Court for a protective order or other appropriate relief no later than fifteen (15) days (as calculated by Fed. R. Civ. P. 6) after receipt of the executed declaration in the form annexed as Exhibit B hereto;

- (c) outside vendors or service providers (such as copy-service providers, jury consultants, and document-management consultants) that counsel hire and assign to this matter;
- (d) any mediator or arbitrator that the Parties engage in this matter or that this Court appoints, provided such person has first executed a Non-Disclosure Agreement in the form annexed as an Exhibit hereto;

- (e) as to any document, its author, its addressee, and any other person indicated on the face of the document as having received a copy;
- (f) any person a Party retains to serve as an expert witness or otherwise provide specialized advice to counsel in connection with this action, provided such person has first executed a Declaration to be Bound by Protective Order in the form annexed as Exhibit B hereto after ten (10) days of delivering the executed Exhibit B (as calculated by Fed. R. Civ. P. 6), unless within that ten (10) day period, the Party receives a written objection from the objecting Party. Any such objection must set forth in detail the grounds on which such objection is based and be made in good faith. A Party that receives a timely written objection must meet and confer with the objecting Party to attempt to resolve the matter. Following the meet and confer, the objecting Party may apply to the Court for a protective order or other appropriate relief no later than fifteen (15) days (as calculated by Fed. R. Civ. P. 6) after receipt of the executed declaration in the form annexed as Exhibit B hereto;
- (g) stenographers engaged to transcribe depositions the Parties conduct in this action; and
- (h) this Court, including any appellate court, its support personnel, and court reporters.

10. Before disclosing any Discovery Material designated under this Order to any person referred to in subparagraphs 8(b), 8(d), 8(f), 8(g), 9(b), 9(d), 9(f), or 9(g) above, counsel must provide a copy of this Order to such person, who must sign a Non-Disclosure

Agreement in the form annexed as Exhibit A hereto stating that he or she has read this Order and agrees to be bound by its terms. Said counsel must retain each signed Non-Disclosure Agreement, hold it in escrow, and produce it to opposing counsel either before such person is permitted to testify (at deposition or trial) or at the conclusion of the case, whichever comes first.

11. In accordance with Rule 5 of this Court's Individual Practices, any party filing documents under seal must simultaneously file with the Court a letter brief and supporting declaration justifying – on a particularized basis – the continued sealing of such documents. The parties should be aware that the Court will unseal documents if it is unable to make “specific, on the record findings . . . demonstrating that closure is essential to preserve higher values and is narrowly tailored to serve that interest.” *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 120 (2d Cir. 2006).

12. The Court also retains discretion whether to afford confidential treatment to any Discovery Material designated under this Order and submitted to the Court in connection with any motion, application, or proceeding that may result in an order and/or decision by the Court. All persons are hereby placed on notice that the Court is unlikely to seal or otherwise afford confidential treatment to any Discovery Material introduced in evidence at trial, even if such material has previously been sealed or designated as Confidential or Highly Confidential.

13. In filing Discovery Material designated under this Order with this Court, or filing portions of any pleadings, motions, or other papers that disclose such Discovery Material (“Designated Court Submission”), the Parties shall publicly file a redacted copy of the Designated Court Submission via the Electronic Case Filing System. The Parties shall file an unredacted copy of the Designated Court Submission under seal with the Clerk of this Court, and

the Parties shall serve this Court and opposing counsel with unredacted courtesy copies of the Designated Court Submission.

14. Any Party who objects to any designation of confidentiality may at any time before the trial of this action serve upon counsel for the Producing Party a written notice stating with particularity the grounds of the objection. If the Parties cannot reach agreement promptly, counsel for all affected Parties will address their dispute to this Court in accordance with paragraph 4(D) of this Court's Individual Practices.

15. Any Party who requests additional limits on disclosure (such as "attorneys' eyes only" in extraordinary circumstances), may at any time before the trial of this action serve upon counsel for the recipient Parties a written notice stating with particularity the grounds of the request. If the Parties cannot reach agreement promptly, counsel for all affected Parties will address their dispute to this Court in accordance with paragraph 4(D) of this Court's Individual Practices.

16. Recipients of Discovery Material designated under this Order may use such material solely for the prosecution and defense of this action and any appeals thereto, and not for any business, commercial, or competitive purpose or in any other litigation proceeding. Nothing contained in this Order, however, will affect or restrict the rights of any Party with respect to its own documents or information produced in this action.

17. Nothing in this Order will prevent any Party from producing any Discovery Material designated under this Order in its possession in response to a lawful subpoena or other compulsory process, or if required to produce by law or by any government agency having jurisdiction, provided that such Party gives written notice to the Producing Party as soon as reasonably possible, and if permitted by the time allowed under the request, at least 10

days before any disclosure. Upon receiving such notice, the Producing Party will bear the burden to oppose compliance with the subpoena, other compulsory process, or other legal notice if the Producing Party deems it appropriate to do so.

18. Each person who has access to Discovery Material designated under this Order must take all due precautions to prevent the unauthorized or inadvertent disclosure of such material.

19. If, in connection with this litigation, a party inadvertently discloses information subject to a claim of attorney-client privilege or attorney work product protection (“Inadvertently Disclosed Information”), such disclosure shall not constitute or be deemed a waiver or forfeiture of any claim of privilege or work product protection with respect to the Inadvertently Disclosed Information and its subject matter.

20. If a disclosing party makes a claim of inadvertent disclosure, the receiving party shall, within five business days, return or destroy all copies of the Inadvertently Disclosed Information, and provide a certification of counsel that all such information has been returned or destroyed.

21. Within five business days of the notification that such Inadvertently Disclosed Information has been returned or destroyed, the disclosing party shall produce a privilege log with respect to the Inadvertently Disclosed Information.

22. The receiving party may move the Court for an Order compelling production of the Inadvertently Disclosed Information. The motion shall be filed under seal, and shall not assert as a ground for entering such an Order the fact or circumstances of the inadvertent production.

23. The disclosing party retains the burden of establishing the privileged or protected nature of any Inadvertently Disclosed Information. Nothing in this Order shall limit the right of any party to request an *in camera* review of the Inadvertently Disclosed Information.

24. Within 60 days of the final disposition of this action – including all appeals – all recipients of Discovery Material designated under this Order must either return it – including all copies thereof – to the Producing Party, or, upon permission of the Producing Party, destroy such material – including all copies thereof. In either event, by the 60-day deadline, the recipient must certify its return or destruction by submitting a written certification to the Producing Party that affirms that it has not retained any copies, abstracts, compilations, summaries, or other forms of reproducing or capturing any of the Discovery Material designated under this Order. Notwithstanding this provision, the attorneys that the Parties have specifically retained for this action may retain an archival copy of all pleadings, motion papers, transcripts, expert reports, legal memoranda, correspondence, or attorney work product, even if such materials contain Discovery Material designated under this Order. Any such archival copies that contain or constitute Discovery Material designated under this Order remain subject to this Order.

25. This Order will survive the termination of the litigation and will continue to be binding upon all persons to whom Discovery Material designated under this Order is produced or disclosed.

26. This Court will retain jurisdiction over all persons subject to this Order to the extent necessary to enforce any obligations arising hereunder or to impose sanctions for any contempt thereof.

SO STIPULATED AND AGREED.

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Dated: July 21, 2022

PERKINS COIE LLP

By: s/ Thomas V. Matthew

Martin E. Gilmore  
Thomas V. Matthew  
1155 Avenue of the Americas,  
22nd Floor  
New York, NY 10036-2711  
Tel: 212-262-6900  
Fax: 212-977-1649  
MGilmore@perkinscoie.com  
TMatthew@perkinscoie.com

Christopher G. Hanewicz  
Andrew T. Dufresne  
David L. Anstaett  
Michael R. Laing  
33 E Main St, Ste 201  
Madison, Wisconsin 53703-3095  
Tel: 608.663.7460  
Fax: 608.663.7499  
CHanewicz@perkinscoie.com  
ADufresne@perkinscoie.com  
MLaing@perkinscoie.com  
DAnstaett@perkinscoie.com

*Attorneys for Plaintiff Allele  
Biotechnology and Pharmaceuticals,  
Inc.*

Dated: July 21, 2022

**LATHAM & WATKINS LLP**

/s/ David P. Frazier

Michael A. Morin (*pro hac vice*)  
David P. Frazier (*pro hac vice*)  
michael.morin@lw.com  
david.frazier@lw.com  
555 Eleventh Street, N.W., Suite 1000  
Washington, D.C. 20004-1304  
Telephone: (202) 637-2200  
Facsimile: (202) 637-2201

Arlene L. Chow  
Michelle L. Ernst  
arlene.chow@lw.com  
michelle.ernst@lw.com  
1271 Avenue of the Americas  
New York, NY 10020  
Telephone: (212) 906-1200  
Facsimile: (212) 751-4864

*Attorneys for Defendant Regeneron  
Pharmaceuticals, Inc.*

Dated: ~~New York, New York~~  
**August 3, 2022**  
**White Plains, New York**

SO ORDERED.



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Philip M. Halpern  
United States District Judge

**EXHIBIT A**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

ALLELE BIOTECHNOLOGY AND  
PHARMACEUTICALS, INC.,

Plaintiff,

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

**NON-DISCLOSURE  
AGREEMENT**

Case No. 7:20-cv-08255 (PMH) (AEK)

I, \_\_\_\_\_, acknowledge that I have read and understand the Protective Order in this action governing the non-disclosure of those portions of Discovery Material that have been designated as Confidential or Highly Confidential under that Protective Order. I acknowledge that in the course of my duties for this litigation I will review materials that have been designated Confidential and/or Highly Confidential (circle the applicable designation) under the Protective Order. I agree that I will not disclose such Confidential or Highly Confidential Discovery Material designated under the Protective Order to anyone other than for purposes of this litigation and that at the conclusion of the litigation I will return all Discovery Material to the Party or attorney from whom I received it. By acknowledging these obligations under the Protective Order, I understand that I am submitting myself to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any issue or dispute arising hereunder and that my willful violation of any term of the Protective Order could subject me to punishment for contempt of Court.

\_\_\_\_\_  
Dated:

**EXHIBIT B**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

ALLELE BIOTECHNOLOGY AND  
PHARMACEUTICALS, INC.,

Plaintiff,

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

**DECLARATION TO BE  
BOUND BY PROTECTIVE ORDER**

Case No. 7:20-cv-08255 (PMH) (AEK)

I, \_\_\_\_\_, declare under penalty of perjury that:

(a) My present address is \_\_\_\_\_

\_\_\_\_\_.

(b) My present employer is \_\_\_\_\_

and the address of my present employer is \_\_\_\_\_

\_\_\_\_\_.

(c) My present occupation or job description is \_\_\_\_\_

\_\_\_\_\_.

(d) I have received and carefully read the Protective Order in the above-captioned action dated \_\_\_\_\_ and understand its provisions. Specifically, I understand that I am obligated, under order of the Court, to hold in confidence and not to disclose the contents of anything marked Confidential or Highly Confidential except as permitted by the Protective Order. I further understand that I am not to disclose to anyone other than those persons permitted access under the Protective Order any words, substances, summaries, abstracts, or indices of any Confidential or Highly Confidential Discovery Material disclosed to me. According to the

restrictions of Paragraph 14 of the Protective Order, I will use Discovery Material, including Confidential or Highly Confidential Discovery Material, or information derived therefrom, solely for purposes relating to the above-captioned action. I will never use Confidential or Highly Confidential Discovery Material or information derived therefrom, directly or indirectly, in competition with the Producing Party nor will I permit others to do so. In addition to the foregoing, I understand that I must abide by all of the provisions of the Protective Order.

(e) I affirm that I will not use any Confidential or Highly Confidential Discovery Materials, or information derived therefrom, for the prohibited activities set forth in Paragraphs 8(b) and 9(b) of the Protective Order.

(e) At the termination of this Litigation or any time requested by outside counsel for the Party by whom I am engaged, I will return or destroy all documents and other materials, including notes, computer data, summaries, abstracts, or any other materials containing or reflecting Confidential or Highly Confidential Discovery Material that have come into my possession, and will return or destroy all documents or things I have prepared relating to or reflecting such information.

(f) I understand that if I violate the provisions of the Protective Order, I will be in violation of a Court Order and subject to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages by the Producing Party. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order in the above-captioned action. I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Respectfully submitted,

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature